

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

In re: TESTOSTERONE )  
REPLACEMENT THERAPY )  
PRODUCTS LIABILITY LITIGATION ) MDL No. 2545  
)  
This document relates to all cases ) Honorable Matthew F. Kennelly

**ABBVIE'S MOTION TO MODIFY CASE MANAGEMENT ORDER NO. 9**

AbbVie respectfully moves this Court for an order modifying Case Management Order No. 9 (the “PFS Order”) because circumstances have changed and the timing provisions in the order are no longer practical or supportive of an informed bellwether selection process. Last fall, when the parties negotiated the PFS Order, which instructs each Plaintiff to submit a completed Plaintiff Fact Sheet (“PFS”) within 45 days after service of Defendants’ answers, the parties expected a steady, rolling stream of PFS and medical records to inform the bellwether selection process. Since that time, however, the parties have engaged in negotiations regarding master and short-form pleadings, which have delayed the filing of answers (and thus the submission of PFS). Combined with the fact that the vast majority of PFS served on AbbVie are deficient (particularly regarding record authorizations), the result has been that *less than 10 percent of the MDL cases against AbbVie have sufficient PFS for medical record collection and review.*

In the meantime, AbbVie and Plaintiffs are scheduled to make a joint submission to the Court regarding bellwether selection on July 11, 2015—less than five months away. AbbVie and Plaintiffs have each expressed a desire for meaningful review of PFS and collection and review of medical records before making any recommendation to the Court regarding the process for bellwether selection. But under the current PFS Order, AbbVie and Plaintiffs will have access to completed PFS and medical records for just a small percentage of Plaintiffs before making their July submission—an unintended, uninformed, and prejudicial result for both parties.

In order for the parties to have any chance of reviewing a more representative set of cases and records, the submission of PFS should no longer be held up by the unrelated status of master pleadings and Defendants' answers to complaints. Despite negotiations, the parties have not been able to reach agreement on a new PFS deadline. Accordingly, AbbVie respectfully requests that CMO 9 be modified to require the service of complaints and the submission of completed and non-deficient PFS, including proper authorizations and production of requested documents (i) within 60 days after the entry of the order granting this motion, for all cases filed before that date, and (ii) within 60 days of the filing of all complaints thereafter. Plaintiffs should bear the burden of submitting non-deficient PFS on such a schedule, and if they cannot do so by the deadlines necessary for the July submission, a change in the schedule clearly is warranted.

## **BACKGROUND**

### **I. The parties' negotiations regarding the PFS Order.**

Defendants moved to dismiss the first 39 cases in this MDL on June 4, 2014. Eight days later, all other responses to complaints in this MDL were stayed. (Dkt. 95.)

In August and September, the parties began negotiating the PFS Order and continued to negotiate a case schedule. Among the issues being negotiated for the case schedule were (i) the date the parties would submit a proposed order on how bellwether Plaintiffs would be selected and (ii) the date those bellwether Plaintiffs actually would be selected.

In the negotiations on the PFS Order, the parties initially disagreed on when PFS should be due for Plaintiffs. Plaintiffs preferred more time to prepare PFS, and Defendants preferred to receive PFS sooner, in order to allow time for the collection and review of medical records. In October, the parties reached a compromise: Plaintiffs who had a case in the MDL as of the date of the PFS Order would submit their PFS by December 29, 2014, while Plaintiffs who filed cases later would submit their PFS within 45 days of receiving the answers of all Defendants.

When Defendants agreed to this compromise, they expected to receive a significant number of PFS for cases that pre-dated the PFS Order. They also expected to receive in short order a ruling on their motion to dismiss. Assuming the cases survived the motion, the ruling would lead to answers, and thus to more PFS, on a rolling basis. Moreover, at that time, Defendants were advocating a schedule in which the bellwether selection process would begin in 2016. That schedule would have allowed Defendants roughly a year and a half to collect PFS and the corresponding medical records for Plaintiffs whose cases were filed after the PFS Order.

## **II. The PFS Order (CMO 9) is entered.**

The Court entered the PFS Order on October 6, 2014. Among other things, the order requires Plaintiffs to “[c]omplete and execute a PFS,” produce responsive and non-privileged documents (including medical and pharmacy records), and “[p]rovide duly executed record release authorizations,” such as medical records authorizations, mental health records authorizations, and employment records authorizations.<sup>1</sup> (CMO 9 at II.A, V.A.)

### **A. The record collection process.**

The PFS Order “designate[s]” Medical Research Consultants (“MRC”) “as Defendants’ plaintiff-specific record management company.” (*Id.* at IV. A.) The order states that once a Plaintiff provides “a completed PFS and/or any information identifying a plaintiff’s healthcare providers, employers, disability providers, and or insurers, MRC, at Defendant(s)’ request, may

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<sup>1</sup> If a Plaintiff fails to submit a PFS or required authorization(s), the Defendant “shall send a warning letter to that Plaintiff’s attorney of record.” (*Id.* at II.E.1.) The parties then have 35 days to meet and confer. (*Id.*) If that Plaintiff still fails to provide either a PFS or authorizations, the Defendant can move to dismiss. (*Id.* at II.E.2.) If a Plaintiff does submit a PFS and authorizations, but they are deficient, the Defendant “shall notify Plaintiff’s attorney of record of the purported deficiencies in writing via email and allow such Plaintiff an additional thirty (30) days to correct the alleged deficiency.” (*Id.* at II.D.1.) If the Defendant still believes the deficiencies have not been cured, it may file a motion to compel. (*Id.* at II.D.2.)

immediate undertake to obtain those records by use of the written authorizations that are provided.” (*Id.* at IV. B.)

It takes approximately 45 days for MRC to collect records from particular healthcare providers, employers, and others that the PFS and accompanying authorizations identify. After those records have been collected, additional healthcare providers and document sources are identified, and it typically takes at least another 45 days to collect those records. Thus, it takes MRC at least 90 days (and usually longer) to collect all records for a particular Plaintiff.

### **III. Subsequent events and unintended consequences.**

As explained below, since the entry of the PFS Order, there have been several significant developments in the litigation: (i) the Court entered a bellwether schedule; (ii) the number of cases in the MDL significantly increased; (iii) the Court denied Defendants’ motion to dismiss (in part) and the parties began to work toward developing a master pleadings CMO; (iv) Defendants began receiving PFS, record authorizations, and records in Plaintiffs’ possession; and (v) a significant number of complaints filed since the PFS Order have still not been served on AbbVie. Each of these events has resulted in unintended consequences detrimental to the PFS Order and the current case schedule regarding bellwether selection.

#### **A. Plaintiffs asked for and received an expedited bellwether schedule.**

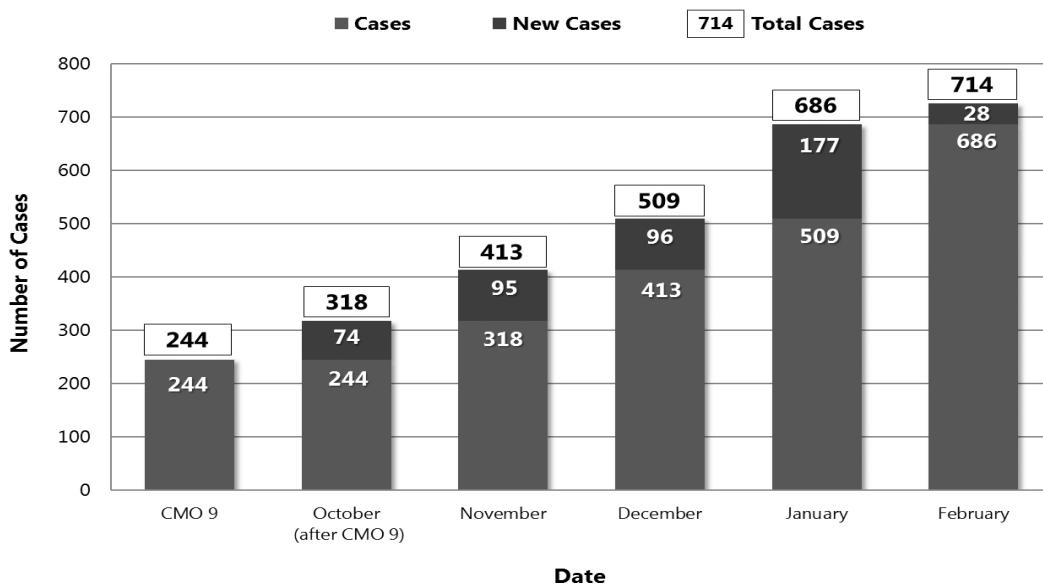
After the PFS Order was entered, the parties continued to negotiate about the case schedule, submitting competing proposals to the Court on October 20, 2014 regarding when the bellwether process would begin. Defendants proposed that the parties submit a CMO on the bellwether process by July 15, 2016, and that the parties select the bellwethers by August 15, 2016. (Dkt. 429-4.) Plaintiffs proposed a far shorter schedule, with the proposed CMO submitted by March 27, 2015 and the bellwethers selected by April 29, 2015. (Dkt. 428-1.)

Nevertheless, Plaintiffs specifically recommended that the parties be allowed “*the opportunity to receive completed Plaintiff Fact Sheets and accompanying medical records before making a recommendation to the Court on what factors are relevant for selection of bellwether cases.*”

(Dkt. 428 at 6 n.8) (emphasis added). After the October 24 status hearing, the parties submitted revised proposals. Then, on November 6, 2014, the Court entered a schedule for AbbVie-only Plaintiffs that required the CMO on the bellwether process to be submitted by July 11, 2015, and the bellwethers selected by October 31, 2015. Thus, the final schedule required the CMO on the bellwether process to be submitted over a year in advance of Defendants’ proposal.

#### **B. There has been a significant increase in cases filed since October.**

At the time of the PFS Order, in early October, there were only 244 cases against AbbVie (and 351 cases against all Defendants) in the MDL. Since that time, the number of cases has risen sharply. As shown in the chart below, by early February there were 714 cases against AbbVie in the MDL. (The total against all Defendants was roughly 1,100.) Thus, the number of cases filed in the four months after the PFS Order was roughly triple the number filed in the eight months prior, as shown below:



**C. Negotiations over a CMO to govern master pleadings remain unresolved.**

On December 23, 2014, roughly two and half months after the PFS Order, the Court largely denied the motion to dismiss. At the end of its order, the Court instructed the parties to confer about “the timing of defendants’ responses to the remaining complaints.” (Dkt. 526 at 31.) By the time of this order, there were over 500 cases in the MDL against AbbVie, more than double the number at the time of the PFS Order.

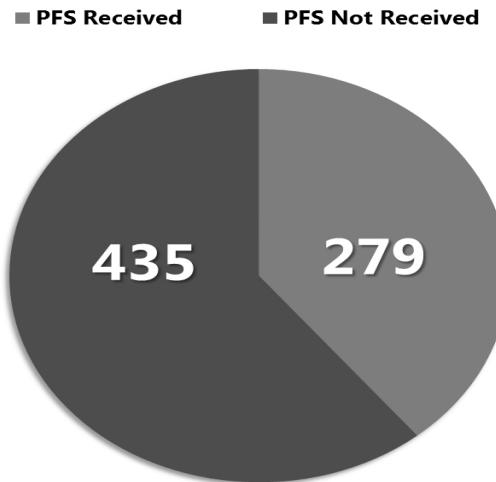
In light of the large number of cases, Defendants proposed to Plaintiffs the use of a master complaint and master answer in an effort to streamline the pleadings. Plaintiffs refused. At the January 13, 2015 status hearing, Plaintiffs stated that they “[did not] believe this litigation . . . is particularly well-suited” for a master complaint and answer. (1/13/15 Tr. at 5.) After arguments by the parties, and the Court’s request to Plaintiffs to “think harder about this,” Plaintiffs “decided it’s probably a good idea for us to do a master complaint.” (*Id.* at 5-12, 40.) After this status hearing, the parties began the process of negotiating a CMO governing master pleadings. Those negotiations are still underway.

**D. Defective PFS and authorizations arrive, along with insufficient records.**

A few weeks earlier, at the end of December, the first round of PFS were due. AbbVie was expecting 244 PFS, of which 181 arrived, 24 were subject to a request for extension (all extensions were granted), and 39 were missing and thus made the subject of warning letters.<sup>2</sup> By mid-February, AbbVie had received all 63 extended and missing PFS, along with another 35 that arrived before they were due, for a grand total of 279, or in other words, PFS for 39 percent of the total cases against AbbVie, as shown below:

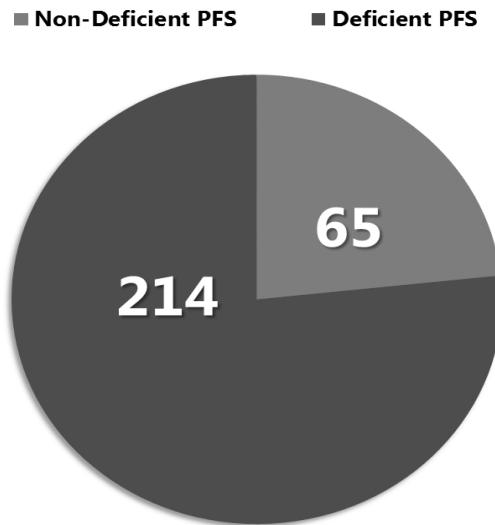
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<sup>2</sup> The 244 number excludes the 8 cases that have been subsequently dismissed by Plaintiffs voluntarily.

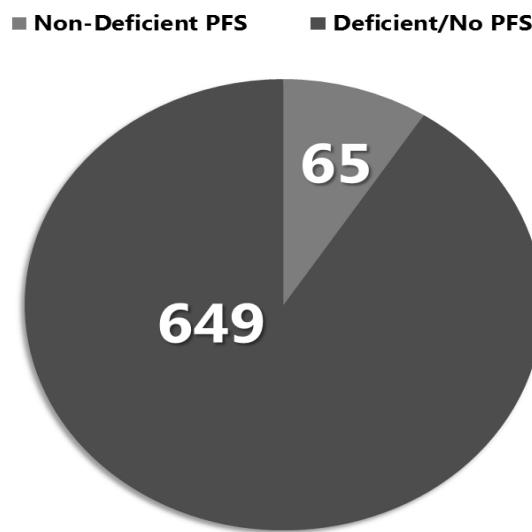


The other PFS have no due date at present, because the master pleadings CMO is still being negotiated, the master complaint has not yet been filed, and so no answers are due. Under the PFS Order, those PFS are due in each case 45 days after the last Defendant in that case answers.

Of the 279 PFS AbbVie has received, over 75 percent (214 of 279) have a record authorization that is deficient for the collection of medical records. Examples of deficiencies in the authorizations include failing to identify a specific healthcare provider, failing to date the authorization, failing to sign the authorization, failing to fully complete the Medicare authorization (e.g., not indicating whether Plaintiff is authorizing the release of all information or just limited information) and so on, as shown below:



These deficiencies prevent AbbVie from collecting complete records for those Plaintiffs. And these are only the deficiencies in record authorizations; the PFS themselves contain other deficiencies not related to records. In sum, at the time of this writing, AbbVie has complete PFS and authorizations for just a small fraction of the Plaintiffs who have cases in this MDL—less than 10 percent, as shown below:



AbbVie brought to the attention of Plaintiffs' Lead Counsel the vast number of PFS with incomplete authorizations that prevent AbbVie from gathering complete records. Lead Counsel stated they would send out communication to their constituents on the matter but that they "could not grant permission" on behalf of Plaintiffs to fill out their authorizations. Defendants did not hear from a single Plaintiffs' attorney granting such permission, despite repeated follow-up with Lead Counsel.

Furthermore, the PFS contains 19 separate requests for documents and records in Plaintiffs' possession, which are treated as document requests under Fed. R. Civ. P. 34 pursuant to the PFS Order. (CMO 9 at II.C.2.) To date, AbbVie has received ***no records from 140 of the 279 Plaintiffs who have submitted PFS.*** While AbbVie does not have authoritative numbers on

precisely what has been produced at this time, AbbVie estimates that it has received approximately 62,000 total pages of records thus far, and that the most common type of records produced has been pharmacy records. The individual productions vary in size, with some of the plaintiffs who have technically produced records producing as little as three pages.

**E. An increasing number of complaints filed are not served on AbbVie.**

Even if the parties come to an agreement on a procedure that sets dates for answers to all complaints, and even if Plaintiffs were to provide complete and non-deficient PFS (including appropriate authorizations and responses to document requests) within 45 days of the last answer to each complaint, AbbVie would still be unable to obtain the necessary information regarding plaintiffs whose cases were filed but not yet served, as the dates for answering the complaints would not yet have begun to run. Plaintiffs have no reasonable basis to unduly delay the service of complaints, particularly because, pursuant to CMO 18, AbbVie has provided an email address through which Plaintiffs may request a waiver of service of process by sending a copy of the summons, complaint, and waiver form. (CMO 18 at II.) Nevertheless, thus far *Plaintiffs have failed to serve AbbVie in over a hundred of the cases filed since the entry of the PFS Order* on October 6, 2014. Below are AbbVie's totals for the number of complaints received and served in currently-active cases as of Friday, February 13.<sup>3</sup>

Date of Complaints	Complaints Filed	Complaints Served on AbbVie
October 7-31, 2014	74	67
November 2014	95	84
December 2014	96	75
January 2015	177	78
February 2015 (to date)	28	9

<sup>3</sup> Again, these numbers exclude cases that were subsequently dismissed by Plaintiffs voluntarily.

### **LEGAL STANDARD**

Case management is an area in which the district court has “considerable discretion.” *E.g., Geremia v. First Nat'l Bank*, 653 F.2d 1, 5 (1st Cir. 1981). A case management order “may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “The use of the good-cause standard, rather than allowing modification only in cases of manifest injustice as is done for other pretrial orders, indicates that there may be more flexibility in allowing some relief.” 6A Charles A. Wright et al., *Federal Practice and Procedure* § 1522.2. Moreover, as noted by the Advisory Committee, “this more liberal standard was included in recognition that the scheduling order is entered early in the litigation and that if a stricter approach to modification were adopted, counsel might be encouraged to request the longest possible time for completing pleading, joinder, and discovery because of a fear that an extension would be impossible.” *Id.*

The hallmark consideration for Rule 16’s good-cause standard is “the diligence of the party seeking the amendment.” *United States v. Alacran Contracting, LLC*, No. 10 CV 50067, 2014 WL 5461391, at \*2 (N.D. Ill. Oct. 27, 2014); *see also Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625-26 (6th Cir. 2002); *Bradford v. DANA Corp.*, 249 F.3d 807, 809 (8th Cir. 2001); *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 340 (2d Cir. 2000); Fed. R. Civ. P. 16, 1983 advisory committee note. Nevertheless, “[w]hat constitutes good cause sufficient to justify the modification of a scheduling order necessarily varies with the circumstances of each case.” 6A Charles A. Wright et al., *Federal Practice and Procedure* § 1522.2. “[T]he existence or degree of prejudice to the party opposing the modification’ and other factors may also affect the decision.” *Bradford*, 249 F.3d at 809 (quoting *Johnson*, 975 F.2d at 609). Courts have found good cause to modify scheduling orders where the requested modification arises from new

circumstances that developed during litigation, *see, e.g., Safeway, Inc. v. Sugarloaf Partnership, LLC*, 423 F. Supp. 2d 531, 539–40 (D. Md. 2006) (allowing belated amendment to complaint), or where delay results from the actions of the opposing party, *see, e.g., Stewart v. Coyne Textile Services*, 212 F.R.D. 494, 496–97 (S.D. W. Va. 2003) (finding “good cause” where delay in filing motion to amend complaint was due to defendant’s late responses to discovery requests). Furthermore, this Court and the Seventh Circuit have made it clear that a core purpose of Rule 16 is to advance litigation through the creation and maintenance of meaningful case deadlines. *See, e.g., Spears v. City of Indianapolis*, 74 F.3d 153, 157-58 (7th Cir.1996); *Johnson v. Methodist Med. Ctr. of Ill.*, 10 F.3d 1300, 1304 (7th Cir.1993); *United States v. Alacran Contracting, LLC*, No. 10 CV 50067, 2014 WL 5461391, at \*2–\*3 (N.D. Ill. Oct. 27, 2014).

## ARGUMENT

This motion presents a clear-cut example of good cause to modify a case management order due to intervening circumstances that will prejudice both the parties’ and this Court’s consideration of an important—potentially paramount—procedural issue. Due to the change in status quo described above, AbbVie now is concerned that the PFS Order is not providing the intended result of completed PFS on a rolling basis for complaints filed in the MDL. Rather, the parties will have insufficient information to make a meaningful recommendation regarding the bellwether selection process unless the PFS Order is modified.

**I. The PFS Order must be modified because insufficient time remains to collect completed PFS, authorizations, and medical records prior to the parties’ joint submission on the bellwether selection process.**

The events described in this motion have combined to deprive AbbVie of the ability to collect completed PFS and adequate medical records in time to inform the parties, or the Court, of the proper bellwether selection process. In order to have time to negotiate a recommendation

on the process for bellwether selection with Plaintiffs, and to analyze the underlying data and determine a sensible process, by July 11, AbbVie must receive completed PFS and records by June 11, 2015—less than four months away. Given that records typically take three months to collect after a non-deficient PFS is received, AbbVie must receive completed PFS and authorizations by March 11. Under the PFS Order, that is simply not possible, because it is less than one month from today, and no answers are yet due.

**A. PFS deadlines should be based on the date the complaint is filed.**

AbbVie and the other Defendants consented to the initial PFS Order at a time when:

(i) AbbVie reasonably expected that it would receive a significant number of complete PFS, for all previously-filed cases, by the end of 2014; (ii) AbbVie reasonably expected that any ruling denying Defendants' motion to dismiss would soon trigger responses to additional complaints, thus in turn triggering new and rolling deadlines for PFS in later-filed cases; and (iii) AbbVie was advocating that the parties be given until July **2016** to submit a proposed CMO on the bellwether selection process. And even after the PFS Order was entered, Plaintiffs themselves recommended to this Court that the parties be given "the opportunity to receive completed Plaintiff Fact Sheets and accompanying medical records before making a recommendation to the Court on what factors are relevant for selection of bellwether cases." (Dkt. 428 at 6 n.8.)

If this Court does not amend the PFS Order, it is likely that (i) answers to Plaintiffs' complaints will not be due for months, thus pushing the deadlines for PFS back to the point that they will be of no use for the bellwether selection process; and (ii) a number of Plaintiffs will continue not to serve their complaints on AbbVie after filing (despite the fact that AbbVie has agreed that waiver of service may be obtained by email), thus skewing bellwether selection and further delaying AbbVie's answers even if a process for answering the complaints were in place.

When the parties agreed to the PFS Order, they certainly did not intend to shut down the PFS submission process and to deprive the parties of the ability to have a meaningful review of PFS and medical records before engaging in the bellwether selection process. Thus, to make the bellwether selection process fair and workable, AbbVie respectfully submits that the timing of PFS be tied to the date of the filing of the complaint itself.

**B. 60 days is reasonable and adequate for Plaintiffs to submit PFS.**

The current deadlines under the PFS Order have been rendered nearly meaningless and conflict with the intention of the parties to move forward toward the process of bellwether selection. Indeed, even though AbbVie had received all required PFS filings (and 35 that were not yet required) by mid-February, that still amounts to PFS in only 279 of the 714 cases against AbbVie, or 39 percent. And while the complaint filings continue to pile up, there is currently no deadline requiring additional PFS to be submitted.

Sixty days from the filing of the complaint (and far more for complaints already filed) is more than reasonable time for submission of the PFS. Any Plaintiff filing a complaint in the MDL should have access to the types of basic information about the claims asserted that are necessary for a complete PFS. Indeed, numerous other litigations have required PFS submission within 45 or 60 days of the filing of a complaint.<sup>4</sup> Therefore, good cause exists for the Court to modify the PFS Order to require the service of the complaint and the submission of complete and non-deficient PFS (i) within 60 days after the entry of the order granting this motion, for all cases filed before that date, and (ii) within 60 days of the filing of all complaints thereafter.

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<sup>4</sup> See, e.g., PTO 16, *In re: Zoloft Prods. Liab. Litig.*, MDL No. 2342, Oct. 15, 2012 (E.D. Pa.) ¶ 7 (45 days) (attached as Ex. 1); PTO 4, *In re: Chantix Prods. Liab. Litig.*, MDL No. 2092, Feb. 24, 2010 (N.D. Ala.) at III.A.2 (60 days) (attached as Ex. 2); PTO 6, *In re: Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, MDL No. 1699, Feb. 13, 2006 (N.D. Ca.) ¶ 5 (60 days) (attached as Ex. 3).

**C. For deadlines to be meaningful, Plaintiffs must submit a completed PFS, proper authorizations, and full responses to Defendants' document requests.**

Furthermore, Plaintiffs' submissions of PFS to date, as detailed above, have been characterized by incomplete or defective record authorizations in the vast majority of cases, and by a scarcity of documents produced by Plaintiffs themselves. Indeed, as of mid-February, 214 of the 279 PFS received by AbbVie have some defect in record authorizations, and AbbVie has received no records whatsoever from 140 of the 279 Plaintiffs who have submitted PFS.

Under the current PFS Order, deficiencies in PFS, records authorizations, or document productions that are submitted are subject to a deficiency letter procedure and potentially a motion to compel if deficiencies are not cured. (CMO 9 at II.D.) Under the timing of the deficiency letter process, it is likely that AbbVie will be unable to obtain complete PFS and other required documents from any deficient Plaintiffs in time to consider those Plaintiffs before the July submission on the bellwether selection process.

Without action by this Court, it is very likely that, despite the mounting number of cases against AbbVie, a very small percentage of cases will have sufficient records to be considered in advance of the first submission on the bellwether process. Therefore, this Court should not only modify the PFS Order as stated above, but must also be clear that Plaintiffs must submit a PFS that includes all of the necessary information, including the proper authorizations and responses to Defendants' requests for document production. If Plaintiffs cannot provide *complete* responses within a timeframe that comports with their own desire to begin the bellwether selection process quickly, then the schedule previously advocated by Plaintiffs must be modified.

**II. AbbVie's requested modification represents a reasonable compromise to maintain the July deadline.**

As stated above, in order for AbbVie to have three months to collect and review medical records, and to have one month to negotiate a bellwether process CMO with Plaintiffs by July

11, AbbVie would need to have complete PFS, including proper authorizations, by March 11. This is exceedingly unlikely under any scenario. Nevertheless, in the interest of compromise AbbVie suggests that Plaintiffs in already-filed cases submit PFS within 60 days of the entry of an order granting this motion. This represents a reasonable compromise should the Court wish to maintain the July 11 deadline.

Entry of this modification will not prejudice Plaintiffs or any party. Indeed, Plaintiffs themselves have agreed that the parties will benefit from having access to complete PFS and collected medical records before making a recommendation to the Court regarding the bellwether selection process. On the other hand, prejudice certainly would result from forcing both AbbVie and Plaintiffs to move forward into the bellwether selection process with a very small number of cases out of what may by then be more than a thousand cases filed against AbbVie in the MDL.

If Plaintiffs cannot substantially comply with the modified CMO, then at a minimum the bellwether schedule should be modified to allow additional time for AbbVie to receive PFS and collect medical records.

### **CONCLUSION**

For the above-stated reasons, AbbVie respectfully request that this Court enter an order modifying Sections V.A-B of Case Management Order 9 to provide that:

- A. Each Plaintiff in a Member Action that is pending as of the date of the entry of the Amended Order shall have 60 days from this date to serve and produce to Defendant the complaint, a completed PFS, signed and dated authorizations, and all responsive, non-privileged documents requested in the PFS that are in his or her possession or custody; and that
- B. Each Plaintiff in a Member Action that is not pending as of the entry of the Amended Order shall have until 60 days from the date of the filing of his or her complaint to serve and produce to Defendant the complaint, a completed PFS, signed and dated authorizations, and all responsive, non-privileged documents requested in the PFS that are in his or her possession or custody.

Dated: February 18, 2015

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Nathan Hoffman, hereby certify that on February 18, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

*/s/ Nathan E. Hoffman*